

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

**In re Lidoderm Antitrust Litigation**

Case No. 14-md-02521-WHO

**ORDER ON MOTION FOR  
RECONSIDERATION AND DISPUTE  
REGARDING CITIZEN PETITION  
DOCUMENTS**

Re: Dkt. Nos. 375, 377, 389, 391

Endo seeks reconsideration of my order rejecting the application of the joint defense/common interest privilege to defendants' discussions on how to allocate costs for the Watson settlement between themselves. Dkt. No. 375. Upon a more complete record, it is apparent that the cost allocation negotiations stemmed from the parties' business relationship, not from their common interest in defending the Watson litigation, and I DENY Endo's motion for reconsideration. The parties also disagree whether the joint defense/common interest privilege extends to discussions between defendants and their consultants about Endo's Citizen Petition and amendments. Dkt. No. 377. Endo and Teikoku had a common commercial interest in the Citizen Petition but not a protectable legal interest concerning their ability to sell Lidoderm or protect related patents, and so documents shared between them concerning the Citizen Petition are not privileged. I address other related privilege and waiver arguments later in this Order.

**I. MOTION FOR RECONSIDERATION**

In my January 12, 2016 Order (Dkt. No. 367), I ruled that two paragraphs<sup>1</sup> of a February 2, 2012, email from Michael Speitz (a Teikoku manager) to Paul Mori (Teikoku's Chief Operating Officer) discussing "how any why Teikoku and Endo proposed to fund the cost of a potential

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<sup>1</sup> The prior Order referred to the information at issue as the fifth and sixth sentences, but as Endo points out, those are more appropriately referred to as the fifth and sixth paragraphs and I will do so in this Order.

settlement with Watson,” could not be shielded from production by the common interest privilege<sup>2</sup> because:

(i) Teikoku and Endo are clearly adverse on this issue which resulted in a separate stand-alone agreement between them; (ii) there is no common legal (as opposed to commercial) interest between them on this issue; (iii) the discussion of this topic as presented in the email was not in furtherance of their joint strategy with respect to the Watson litigation; and (iv) there is no evidence that how the settlement will be funded as between Teikoku and Endo was a necessary part of either Teikoku or Endo’s agreement to settle the Watson litigation (and any such assertion would be belied by the fact that the final cost split between Teikoku and Endo was only agreed to significantly after the Watson settlement was reached).

Dkt. No. 367 at 1-2. Endo filed a motion for leave to seek reconsideration of that ruling and/or to certify that issue for interlocutory appeal. Dkt. No. 375. I asked plaintiffs to file a brief in response to Endo’s motion. Dkt. No. 379. Plaintiffs oppose the motion for reconsideration, arguing that Endo has not satisfied the Civil Local Rule 7-9 requirements for seeking reconsideration (diligence, existence of new law or facts, etc.). While that may be true, in my discretion, I will consider the motion for reconsideration on the merits.<sup>3</sup>

Endo argues that my prior ruling was wrong in light of facts that were not in front of the Court<sup>4</sup>--namely, that while Endo and Teikoku did not enter into a formal supplemental agreement governing the split of the costs of the Watson settlement agreement until after the May 28, 2012, Watson settlement was reached, Endo and Teikoku reached an agreement in principle between themselves that they would equally share the cost of the main Watson settlement provision (providing free product) no later than May 9, 2012. *See* Declaration of Noriyuki Shimoda (Dkt. No. 375-2), ¶ 7. Because Endo and Teikoku were “contractually required to obtain Teikoku’s consent to the settlement with Watson in certain circumstances,” Endo argues it was not at all

<sup>2</sup> The privilege is variously referred to as the common interest or joint defense privilege. For simplicity, I will refer to it as the common interest privilege in this Order.

<sup>3</sup> The Administrative Motion to Seal portions of plaintiffs’ opposition to the motion for reconsideration and Exhibits 6-9, 11-12 of the Sharp Decl.(Dkt. No. 389) is GRANTED. Good cause has been shown (Dkts. No. 393, 394) to seal that information for purposes of this discovery dispute.

<sup>4</sup> This issue was first raised – along with other substantive issues – in the parties’ December 17, 2015, five page Joint Discovery Letter. Dkt. No. 358-4. Endo contends that it was unable to present all relevant facts and case law, given the Court’s five page limit and expedited briefing process.

surprising that Endo and Teikoku needed to discuss their strategies and corresponding responsibilities with respect to the ongoing Watson settlement negotiations. According to Teikoku's outside counsel, Noriyuki Shimoda, the purpose of the meeting memorialized in the February 2nd email was for counsel and decision-makers at Endo and Teikoku to "solidify" their joint efforts in connection with the litigation and possible settlement of the Watson litigation. Shimoda Decl. ¶ 4. Shimoda declares that Endo and Teikoku "discussed the allocation of settlement costs in order to decipher whether Endo and Teikoku would be able to reach a mutually agreeable settlement with Watson, and on what terms." *Id.* ¶ 5. He characterizes the ongoing discussions on this topic between the companies in April and early May 2012 "as a basic step in advancing their joint settlement of the '529 litigation with Watson." *Id.* ¶ 6.

Defendants' contemporaneous communications and agreements contradict those assertions. Communications between Endo and Teikoku show that prior to the May 9, 2012 "agreement in principle" between Endo and Teikoku, Endo and Watson were exchanging significant and detailed settlement offers. Declaration of Dena C. Sharp (Dkt. No. 390-2), Exs. 5-9. Although Shimoda says that the purpose of the February 2, 2012 meeting was to "decipher" whether Endo and Teikoku would be able to reach a mutually agreeable split of the costs, Endo made at least one significant offer to Watson *prior* to the February 2, 2012 email at issue. Sharp Decl., Ex.6. Plaintiffs also point out that Teikoku's CEO testified before the FTC that the final cost split with Endo was not agreed to until "two to three" months after the Watson settlement. Sharp Decl. Ex. 10. Evidence relied on by plaintiffs confirms that details of how exactly the cost of the settlement would be split – given various business and tax consequences to Endo and Teikoku – were still being negotiated well after the May 28, 2012 Watson settlement was reached, including how Endo and Teikoku would split the royalties from Watson's sale of brand name Lidoderm patches. Sharp Decl., Ex. 12.

Even more significant, Endo and Teikoku's 2007 Agreement provided that the cost of any Paragraph IV litigation (like the Watson litigation) was to be funded by Endo. Dkt. No. 301-16. As counsel for Teikoku admitted at the March 1, 2016 hearing, Teikoku believed it did not have an obligation to fund any portion of the proposed or eventual settlement with Watson, but agreed

to in order “protect the good business relationship” with its “long term” partner Endo. The cost split, therefore, was a decision to further Teikoku’s and Endo’s own ongoing *business* relationship. In light of the fact that Teikoku was not obligated to share in the costs of settlement and given the contemporaneous documents, there is little evidentiary support for the proposition that an agreement on the cost split between Teikoku and Endo was a “necessary predicate” to the Watson settlement.

Endo also argues my prior ruling was wrong on the law, relying on cases not cited in the parties’ December 17, 2015 Joint Dispute Letter. Endo contends that I took too “granular” a view by finding that although Endo and Teikoku had a common interest in their joint prosecution and settlement of the Watson litigation, their common interest did not extend to allocation of the liabilities for the proposed settlement because Endo and Teikoku were adverse on that issue. Endo relies on two cases that arose in the context of arbitration proceedings whose sole purpose was to resolve joint defense parties’ liability for costs related to their joint defense. *See Arkema Inc. v. Asarco, Inc.*, No. C05-5087 RBL, 2006 WL 1789044 (W.D. Wash. June 27, 2006); *see also Roper v. Old Republic Ins. Co.*, No. 09-C-154, 2010 WL 424598, at \*1 (E.D. Wis. Feb. 1, 2010). These cases, however, are factually inapposite. Here, Endo bore the cost of the Watson litigation and Teikoku’s obligation to split costs for the proposed settlement was voluntary and a matter of, as its counsel said, “good business.” That was certainly not the case in *Arkema* or *Roper*, where the parties acknowledge joint fault and agreed to arbitrations specifically to allocate their various liabilities. Also, as recognized by both decisions, the arbitration proceedings and ultimate decisions were initiated *after* the underlying claims arose. The arbitrations, therefore, were “internal” to the defense and not relevant to the underlying litigation. *Roper*, 2010 WL 424598, at \*2; *Arkema*, 2006 WL 2254478, at \*2. This case is different, where the reasons that Endo and Teikoku entered into the Watson settlement are central to the merits of this case.<sup>5</sup>

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<sup>5</sup> Endo also relies on *Griffith v. Davis*, 161 F.R.D. 687, 693 (C.D. Cal. 1995), where the court noted that for a common defense privilege to apply, the interest at issue need not be identical and may be adverse in some respects. That case, however, did not attempt to identify where a common interest privilege might end. Instead in that case – a Federal Tort Claim Act and *Bivens* action against an IRS agent and eventually the United States – the court determined that a joint defense existed overall because the claims against both the IRS agent and the United States

As I noted in my prior ruling, the statements at issue must be in furtherance of the strategy with respect to the joint litigation in order to be covered by the common interest privilege. *See, e.g., In re Imperial Corp. of Am.*, 167 F.R.D. 447, 455 (S.D. Cal. 1995) *aff'd*, 92 F.3d 1503 (9th Cir. 1996).<sup>6</sup> As shown by the evidence before me, the comments at issue in the February 2, 2012, email regarding the cost split between Endo and Teikoku cannot have been in furtherance of the parties' joint strategy *with Watson* where: (i) Endo bore the costs of the Watson litigation; (ii) Teikoku decided to pay for some of the costs of the Watson settlement as a business matter; (iii) Endo made a substantial settlement offer prior to the February 2nd email; (iv) additional offers were made before the May 9, 2012, agreement in principle between Endo and Teikoku; and (v) significant aspects of the settlement between Endo and Teikoku were being negotiated well after the May 29, 2012, settlement with Watson. The factual predicate of this case is much more similar to cases finding that although parties might have a common interest, for example in the validity of patents being negotiated for sale, negotiations of those own parties' "rights and relationships to each other are not to be protected, as the parties' interests would have been adverse rather than common." *Mondis Tech., Ltd. v. LG Elecs., Inc.*, No. 2:07-CV-565-TJW-CE, 2011 WL 1714304, at \*4 (E.D. Tex. May 4, 2011) (quoting *Rembrandt Techs., L.P. v. Harris Corp.*, No. CIV.A. 07C09059JRS, 2009 WL 402332, at \*7 (Del. Super. Feb. 12, 2009)). Endo has failed to show that the common interest privilege covers the discussions on how to split the costs of a settlement with Watson.

As to Endo's request for certification of this issue for interlocutory appeal, it argues that my prior ruling has "special consequences" because the document at issue concerns a central issue in the case and it would be impossible to undo the prejudice caused by the disclosure of the otherwise protected attorney-client privileged information. 28 U.S.C. § 1292(b) permits a district

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"involve similar allegations based upon the same incident. Further, defendants face a common adversary." *Id.* at 693.

<sup>6</sup> In *In re Imperial Corp. of Am.*, 167 F.R.D. 447 (S.D. Cal. 1995), the court refused to extend the "common defense privilege" to a demand letter from an insured to its insurer as "the letter constitutes a normal business communication between an insured and an insurer, with the insured having the contractual obligation to keep the insurer informed about the insured's insurance claim with the insurer." *Id.* at 455.

1 court to certify an order for interlocutory appellate review where the order involves: (i) “a  
2 controlling question of law;” (ii) “as to which there is substantial ground for difference of  
3 opinion;” and (iii) where “an immediate appeal from the order may materially advance the  
4 ultimate termination of the litigation.” 28 U.S.C. § 1292(b). The party seeking the interlocutory  
5 appeal bears the burden of showing that all three requirements have been met. *Couch v. Telescope*  
6 *Inc.*, 611 F.3d 629, 633 (9th Cir.2010). Moreover, “[c]ertification under § 1292(b) requires the  
7 district court to expressly find in writing that all three § 1292(b) requirements are met.” *Id.*

8 I agree with Endo that there is substantial ground for difference of opinion on whether the  
9 common interest privilege – that I have already found protects against disclosure of joint strategy  
10 discussions between Endo and Teikoku about the potential settlement with Watson – extends to  
11 separate discussions between those parties concerning how the costs of settlement would be split.  
12 However, that narrow question is not a “controlling question of law” on the merits of this case, nor  
13 is it apparent that immediate determination of that issue would materially advance the ultimate  
14 termination of the litigation. The request for certification for interlocutory appeal is DENIED.  
15 However, in order to allow Endo to seek mandamus relief from the Ninth Circuit, defendants need  
16 not produce the information at issue for thirty days (30) from the date of this Order, absent further  
17 order from the Ninth Circuit.<sup>7</sup>

## 18 **II. CITIZEN PETITION**

19 Endo filed its first Citizen Petition with the FDA regarding Lidoderm in 2006 and filed its  
20 first amendment to the Petition in 2007. Endo was the only signatory on the Petition and the  
21 amendment. A second amendment was filed, again signed only by Endo, in 2012. The parties  
22 dispute whether discussions between Endo and Teikoku about Endo’s Citizen Petition and its  
23 amendments are covered by the common interest privilege, and whether any applicable privilege  
24 has nonetheless been waived for communications from and to third-party consultants hired by  
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27 <sup>7</sup> As discussed at the hearing, if plaintiffs are deprived of their ability to use this information (and  
28 other documents containing similar information) while fact discovery is ongoing and depositions  
occurring while defendants seek appellate review, I will consider reasonable requests to recall  
deponents and for limited additional discovery.

1 Endo.<sup>8</sup>

2 According to Caroline Manogue – the former Endo General Counsel – the purpose of  
3 Endo’s Citizen Petition was to request that the FDA “follow its own guidelines by, among other  
4 things, requiring comparative clinical efficacy studies to establish bioequivalence for” any ANDA.  
5 Manogue Decl. (Dkt. No. 386-1), ¶ 4. Manogue declares that she provided legal review and  
6 analysis concerning the contents of the Citizen Petition filings and whether and when to file the  
7 2012 Amendment. *Id.* ¶ 6.

8 **A. Does the Common Interest Privilege Extend to Endo’s Citizen Petition and**  
9 **Amendments?**

10 I must first determine whether – assuming the underlying documents are protected by the  
11 attorney-client privilege, an issue I address below – the sharing of information between Endo and  
12 Teikoku waived that privilege or whether their “common interest” in the success of Endo’s Citizen  
13 Petition is sufficient to maintain the privilege. The starting point for this analysis must focus on  
14 the purpose of the Citizen Petition. As Manogue explains, the purpose of the Citizen Petition was  
15 to ensure that the FDA adhered to its own regulations when considering ANDA’s for generic  
16 Lidoderm by, among other things, requiring clinical efficacy studies to establish bioequivalence.  
17 Manogue Decl. (Dkt. No. 386-1) ¶ 4. As described in the Petition itself, its purpose was to protect  
18 the public by “requiring generic manufacturers to conduct comparative clinical efficacy trials to  
19 demonstrate bioequivalence is necessary to ensure that any generic lidocaine topical patch, 5%  
20 product is as safe and effective and produces the same unique analgesic effect without complete  
21 sensory block as Lidoderme, and moreover, to comply with FDA’s own regulations.” 2006  
22 Citizen Petition at 2-3 ([http://www.regulations.gov/#!documentDetail;D=FDA-2006-P-0346-](http://www.regulations.gov/#!documentDetail;D=FDA-2006-P-0346-0006)  
23 [0006](http://www.regulations.gov/#!documentDetail;D=FDA-2006-P-0346-0006)). Manogue asserts that although Teikoku was not a signatory to Endo’s Citizen Petition or  
24 its amendments, their interests were aligned “in seeking a ruling from the FDA concerning the  
25 proper interpretation and application of its bioequivalence regulations.” Manogue Decl. ¶ 16.

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28 <sup>8</sup> The Administrative Motion to Seal portions of plaintiffs’ reply in support of their motion and Exhibits 3, 4, 6, and 7 of the Sharp Decl. (Dkt. No. 392-1) is GRANTED. Good cause has been shown (Dkt. No. 396) to seal that information for purposes of this discovery dispute

Manogue’s assertion may well be true, but the common interest privilege protects documents shared between parties who have a common *legal* interest; it does not extend to and cannot protect disclosure of communications regarding a common *business* interest. *See, e.g., Nidec Corp. v. Victor Co. of Japan*, 249 F.R.D. 575, 578 (N.D. Cal. 2007) (“that legal assistance must pertain to the matter in which the parties have a joint legal interest, and the communication must be designed to further that specific legal interest.”); *see also In re Pac. Pictures Corp.*, 679 F.3d 1121, 1129 (9th Cir. 2012) (“a shared desire to see the same outcome in a legal matter is insufficient to bring a communication between two parties within this exception”); *United States v. Bergonzi*, 216 F.R.D. 487, 496 (N.D. Cal. 2003) (rejecting application of common interest doctrine where the interest alleged “is not like the interest shared by allied lawyers and clients who are working together in prosecuting or defending a lawsuit.”). Here, while Endo and Teikoku shared a “common interest” in wanting to see the FDA adhere to its regulations, those interests were commercial, not legal. The tougher the FDA made it for approval of an ANDA relying on Lidoderm, the longer Endo and Teikoku could maintain their sole manufacturer/distributor positions. The Citizen Petition process had nothing to do with obtaining or continuing the FDA’s approval of Lidoderm, the drug in which they both had a protectable legal interest. Instead, their shared interest was to keep generic drugs off the market.

Endo points out that courts have applied the common interest doctrine to protect communications between patent holders and exclusive licensees with respect to proceedings before the PTO because both entities share a common legal interest: the issuance and enforceability of the underlying patents. *See, e.g., In re Regents of Univ. of California*, 101 F.3d 1386, 1390 (Fed. Cir. 1996) (“we conclude that the legal interest between Lilly and UC was substantially identical because of the potentially and ultimately exclusive nature of the Lilly–UC license agreement. Both parties had the same interest in obtaining strong and enforceable patents.”). But that is simply not the case here, where Endo and Teikoku’s common interest was keeping other drugs off the market, whether the justification was for commercial or public safety reasons.

The distinction between legal and commercial interests is supported by the decision in *In*

1 *Re: Diet Drugs*, 2001 WL 34133955 (E.D. Pa. Apr. 19, 2001), relied on by both plaintiffs and  
 2 defendants. There, the court drew a distinction between the types of documents shared between  
 3 the holder of two drug patents and its two exclusive licensees (one for each drug) concerning  
 4 whether the common interest privilege shielded disclosure of otherwise privileged documents. As  
 5 to documents regarding patent prosecution, potential product liability lawsuits against all three,  
 6 and documents which pertained to obtaining and maintaining FDA approval, the court found there  
 7 was a common interest sufficient to protect the privilege. *Id.* at \*6-7. The efforts of the parties to  
 8 get and maintain the FDA's approval for the drugs they each had *legally protectable* interests in  
 9 were covered by the common interest privilege. But there was no evidence that the parties shared  
 10 a common legal, as opposed to commercial interest, regarding the efforts of one of the licensees to  
 11 have *its* drug descheduled under the Controlled Substances Act, because only that licensee had  
 12 duty to seek descheduling. *Id.* at \*7.

13 The aim of the Citizen Petition was not to seek or maintain approval of Lidoderm, but  
 14 instead to convince the FDA to maintain higher standards and keep competing generics off the  
 15 market until they met those higher standards. That is a common commercial interest of Endo and  
 16 Teikoku. The fact that Endo was making a *legal* argument among others in its Petition (that the  
 17 FDA should adhere to its own regulations for bioequivalence) does not turn Endo and Teikoku's  
 18 joint commercial interest into a legal one.<sup>9</sup>

19 In light of the accepted approach that privileges should be construed narrowly, *United*  
 20 *States v. Weissman*, 195 F.3d 96, 100 (2nd Cir, 1999), many courts have refused to extend the  
 21 common interest doctrine to joint regulatory or lobbying efforts. *See, e.g., United States v. Duke*  
 22 *Energy Corp.*, 214 F.R.D. 383, 390 (M.D.N.C. 2003) (rejecting argument that "whenever a  
 23 business group bands together for a common purpose of making their will known to government  
 24 regulators, all attorney communication to the group is privileged and/or work product," as that  
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26 <sup>9</sup> At the hearing, counsel for Endo and Teikoku emphasized the "legal" interest both entities had  
 27 in making sure the FDA complied with its own regulations. But that "legal" interest is far too  
 28 generalized to support a finding under the "common interest" doctrine. Every brand name drug  
 distributor and patent holder would have a similar "legal" interest. Application of the "common  
 interest privilege" based on that rationale would unduly expand its reach.

would be “a drastic expansion of the law of privilege and work product protection.”); *Bowman v. Brush Wellman, Inc.*, No. 00 C 50264, 2001 WL 1339003, at \*3 (N.D. Ill. Oct. 30, 2001) (documents shared between companies involved in regulatory proceedings “to ensure that the standards set through the regulatory proceedings were fair and accurate” were not “legal” and instead related to a common business interest, to obtain favorable results in regulatory proceedings).<sup>10</sup> Where the relief Endo sought at the FDA was not to protect its legal interests in its ability to sell Lidoderm (or Teikoku’s legal interests in protecting the strength of its patents covering Lidoderm), but simply to have the FDA adhere to its own regulations in order to keep other drugs off the market, defendants’ interests were commercial.

Defendants have not shown that they have a common legal interest in the Citizen Petition and its amendments that would protect otherwise privileged attorney client documents that were shared between them from disclosure. All communications and documents regarding Endo’s Citizen Petition and amendments that were shared between Endo and Teikoku must be produced.<sup>11</sup>

#### **B. Are Communications at Issue Covered by Attorney-Client Privilege?**

To the extent that there are documents regarding the Citizen Petition that were not shared between Endo and Teikoku, those documents may be protected from disclosure by the attorney-client privilege, but only to the extent the communications or documents contain legal advice regarding the Citizen Petition and its amendments or were made in order to allow Endo’s or Teikoku’s outside or in-house counsel to provide legal guidance regarding the Petition process. As both sides recognize, communications from or to legal counsel regarding the substantive preparation and strategy regarding the Citizen Petition and its amendments are generally protected

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<sup>10</sup> Defendants rely on *Broessel v. Triad Guar. Ins. Corp.*, 238 F.R.D. 215, 220 (W.D. Ky. 2006), where the court noted in passing that the common interest privilege could protect communications regarding “legislative and regulatory matters, as well as in matters in litigation.” The court did so, however, only after acknowledging a shared legal interest was demonstrated because the group of several members of the mortgage industry pooled their “resources to prepare a common or united defense to the claims asserted in an alleged class action suit.” The court also applied the rule that the common interest privilege “does not encompass a joint business strategy which happens to include as one of its elements a concern about litigation.” *Id.* at 220 n.3.

<sup>11</sup> As discussed below, this does not include comments of counsel shared between Endo and Teikoku regarding the timing of the Citizen Petition amendments in light of counsel’s concerns with the Watson litigation. Those comments are squarely relevant to Endo and Teikoku’s common interest in the Watson litigation and potential settlement.

by the attorney-client privilege. *See, e.g., Barba v. Shire US, Inc.*, No. 13-21158-CIV, 2015 WL 2412257, at \*5 (S.D. Fla. May 20, 2015) (drafts of petition made by legal counsel and notes memorializing “outcome of a meeting with the legal team concerning the current status of the preparation of the ‘Citizen’s Petition’ and a plan forward” were privileged); *In re Prograf Antitrust Litig.*, No. 1:11-MD-02242-RWZ, 2013 WL 1868227, at \*2 (D. Mass. May 3, 2013). (“Communications from Astellas’s in-house counsel Catherine Wertjes to outside counsel made, in confidence, for the purpose of seeking or receiving legal advice regarding the drafting and filing of the Citizen Petition are protected by the attorney-client privilege.”).

However, a communication is not protected simply because a document deals with the Citizen Petition and an attorney or attorneys are on the recipient list for communications. *See, e.g., In re Mirapex Products Liab. Litig.*, No. 06 CV 1215 JMR/FLN, 2008 WL 7505585, at \*1 (D. Minn. July 10, 2008) (communications from non-legal employee to two doctors and a lawyer regarding courses of conduct company may take in response to FDA communications not protected, where “input sought is not legal advice” and no legal advice was given in response). For example, in *Barba v. Shire US, Inc.*, 2015 WL 2412257, at \*3 - \*5, the court concluded that the portions of email strings that did not specifically allude to legal advice were not protectable, even where attorneys were copied, because the emails were not directed at the attorneys. Also not protected were documents discussing the “scientific rationale” and “interdependencies” with other drugs. *Id.* at \* 4. However, some portions of the same email strings that contained attorney-client advice were protectable, as was the attached draft Citizen Petition. *Id.*; *see also In re Prograf Antitrust Litig.*, No. 1:11-MD-02242-RWZ, 2013 WL 1868227, at \*2 (D. Mass. May 3, 2013) (communications by in-house counsel concerning “business matters, including the petition’s factual and technical content, objective merit, and timing of filing, are not privileged.”); *cf. King Drug Co. of Florence v. Cephalon, Inc.*, No. 2:06-CV-1797, 2011 WL 2623306 (E.D. Pa. July 5, 2011) (communications discussing little more than potential launch scenarios for generic manufacturers are business, not legal, communications even if based on “feedback” from a lawyer).

Despite the fact that many of the documents submitted for *in camera* review should be

disclosed because they concerned the Citizen Petition and were shared between Endo and Teikoku, I will provide my thoughts on whether the documents actually contain attorney-client privileged information, as opposed to general business information, in order to provide guidance to the parties regarding defendants' ongoing assertions of privilege.

In general, it appears that defendants have taken an overly expansive view of which documents are privileged simply because Ms. Manogue and other attorneys (either at PWR, whose role is discussed more in-depth below, or at Teikoku) drafted them or were copied on them. Some of the documents submitted for *in camera* review are devoid of legal advice, but concern business matters. For example, Exhibit 3 [A00001754862] is a chain of emails attaching a draft of the Citizen Petition amendment.<sup>12</sup> The emails concern the purpose of a Citizen Petition and the timing for filing, which read in context are business matters not legal advice or communications seeking legal advice.<sup>13</sup> Exhibits 5, 6 & 7 consist of a cover email and identical "Citizen Petition Timeline" slides. There is no legal advice contained or sought in the email or slides, and the slides themselves appear to be based on publicly available information, plus what may be an internal plan or suggestion on timing for an additional Citizen Petition amendment. These documents are devoid of legal advice. While they may have been prepared for a discussion between Endo, Teikoku, and PWR as to the timing of a Citizen Petition amendment or whether to file a new Citizen Petition, that does not make the contents of the emails and identical slides protectable as attorney-client information.<sup>14</sup> Exhibit 8 [P\_ENDO-LID-AT0013337] is a cover email from Caroline Manogue to board members and others at Endo attaching the response from the FDA denying the Citizen Petition. That email was forwarded by Endo's former CFO Levin to additional people at Endo seeking input on various business matters, and an email response to Levin from one of the subsequent recipients about expected financial reporting in response to the FDA's action. These documents are concerned with the business implications of the FDA's

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<sup>12</sup> The draft was not attached to the *in camera* submission. Therefore, I do not reach the question of whether this or any other drafts can be withheld under the attorney client privilege.

<sup>13</sup> This document must be disclosed anyway because it related to the Citizen Petition and amendments and was shared between Endo and Teikoku.

<sup>14</sup> These documents must be disclosed anyway because they were shared between Endo/PWR and Teikoku.

actions. Other than the first sentence at the top of the email chain (regarding a conversation with Manogue), there is no legal advice provided or sought. Other than that one sentence, this communication is not protected by the attorney-client privilege.

Exhibit 9 [P\_ENDO-LID-AT0013782] is an email string. The first two emails contain comments between apex executives at Endo and Teikoku (copied to Manogue) regarding the status, timing, and content of Dr. Harapanhalli's draft of proposed amendments to the Citizen Petition, as well as thoughts on whether to resubmit the existing Citizen Petition or file new requests with the FDA. While the emails indicate that Endo needs to secure approval by "senior management" on the final Citizen Petition amendments, there is no legal advice included in or sought by these two emails.<sup>15</sup> The third email is one between David Lee at Endo and PWR (whose status is discussed below) and Manogue. This email could be construed as a communication seeking legal advice and may be protected as attorney-client privilege. Exhibit 10 [P\_ENDO-LIT-AT0026248] is an email from an Endo employee attaching a draft press release, fact sheet, and "message map" drafted in coordination with a PR firm regarding the Citizen Petition shared with other Endo employees, including Manogue, and PWR. The top email is a forward of the same between two Endo employees. These documents do not seek or contain attorney-client privileged information. They are business communications that must be produced.<sup>16</sup> Exhibit 11 [A00000077736] is an email chain containing emails between Teikoku employees and executives and Dr. Harapanhalli, discussing Dr. Harapanhalli's suggestions for Endo's communications with the FDA. The senders and recipients are not attorneys at Teikoku, and the contents of the emails appear to be strategies suggested by Dr. Harapanhalli (who is not an attorney). No legal advice is sought or included, and these communications must be disclosed. Exhibit 12 [A00000262775] is a string of emails (two of which were discussed in Exhibit 10 and not protectable) of comments regarding Dr. Harapanhalli's suggested strategies, as well as Endo's concerns regarding the timing of the proposed amendments and an email between an executive at

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<sup>15</sup> These two emails must be disclosed anyway because they relate to the Citizen Petition and amendments and were shared between Endo and Teikoku.

<sup>16</sup> These documents were shared with Apco Worldwide, a communications firm, and therefore even if they were privileged, that privilege would be waived.

1 Teikoku and Endo (as to which Manogue and PWR are copied) forwarding Dr. Harapanhalli's  
2 draft Citizen Petition. These emails do not contain or seek legal advice. At most, the thoughts of  
3 Endo's "senior management" are sought. These documents must be disclosed.<sup>17</sup>

4 Other documents or portions of documents, however, are clearly covered by the attorney-  
5 client privilege because they contain advice of counsel. These include the documents that reflect  
6 Ms. Manogue's comments regarding the timing of the Citizen Petition made in the specific context  
7 of and out of concern with the Watson settlement: Exhibit 1 [TEI-AT0304130] (discussing  
8 counsel's thoughts on the status of Watson litigation relevant to timing of the Citizen Petition  
9 amendments); Exhibit 2 [A00000328444] (discussing Citizen Petition in context of Watson  
10 litigation settlement discussions); and Exhibit 4 [TEI-AT0071010] (same).<sup>18</sup>

### 11 **C. Has Any Privilege Been Waived for Communications To/From Consultants?**

12 To the extent there are documents at issue discussing the Citizen Petition that were not  
13 shared between Endo and Teikoku, and were not solely business matters, plaintiffs also argue that  
14 because some of these documents were shared with two outside consultants, any privilege has  
15 been waived.

16 The first entity is PWR Strategies, a law firm specializing in "biomedical matters,"  
17 including regulatory matters with the FDA and consisting of Matthew Peterson (attorney) and Ken  
18 Wilmarth (scientist). Declaration of Matthew Peterson (Dkt. No. 386-2), ¶¶ 2, 3, 6. Endo signed a  
19 retainer with PRW for "strategic services." Ex. 13. That retainer could be cancelled if a Generic  
20 for Lidoderm was approved by FDA. *Id.* Peterson explains that he was hired (at his prior law  
21 firm) to provide legal advice to Endo on the 2006 Citizen Petition, which "generally speaking"

22  
23 <sup>17</sup> These emails must be disclosed anyway because they relate to the CITIZEN PETITION and  
24 amendments and were shared between Endo and Teikoku

25 <sup>18</sup> While documents regarding the Citizen Petition and its amendments are not covered by the  
26 common interest privilege, as discussed above, the particular comments at issue regarding timing  
27 of the proposed Citizen Petition amendments in light of the ongoing Watson litigation are covered  
28 because those are directly relevant to the parties' joint strategy in litigating and/or settling the  
Watson litigation. This conclusion is not contrary to *King Drug Co. of Florence v. Cephalon, Inc.*,  
No. 2:06-CV-1797, 2011 WL 2623306 (E.D. Pa. July 5, 2011). The communication there –  
comments by defendant's drug supplier as to the launch of generics – did not reveal attorney-client  
privileged information because the primary purpose of that communication, was not to gain or  
provide legal assistance. *Id.* at \*7.

1 requested the FDA to adhere to its regulations and to “require comparative clinical efficiency  
2 studies” for any ANDA. Peterson Decl., ¶ 4. His new firm provided similar services with respect  
3 to the 2012 amendment. *Id.* ¶ 6. Manogue testified to the FTC that PWR was hired to help draft  
4 and were the primary drafters of the 2012 supplement to Endo’s Citizen Petition. Asimow Decl.  
5 (386-3), Ex. A (Manogue FTC testimony). Manogue also declares that PWR was retained to act as  
6 outside counsel to provide “legal advice” on whether to amend the Citizen Petition and the content  
7 of any amendment in 2012. Manogue Decl. ¶ 10.

8 Based on the evidentiary record before me, I conclude that PWR can be considered Endo’s  
9 outside counsel and there was no waiver of attorney-client privilege when otherwise privileged  
10 communications were shared between Endo and PWR.

11 The second entity is Dr. Harapanhalli at Parexel International. Endo has submitted an  
12 agreement between *Teikoku* and Dr. Harapanhalli from June 2011, but that agreement appears to  
13 cover another product and does not appear to be directly related to the Lidoderm Citizen Petition.  
14 Exhibit 14. Matthew Peterson from PWR declares that to provide legal counsel to Endo regarding  
15 the 2012 amendment, he had to work with third-party consultants. Those consultants included Dr.  
16 Harapanhalli, who was consulted by PWR regarding potentially amending or supplementing the  
17 Citizen Petition, because PWR needed his chemistry and manufacturing controls expertise.  
18 Peterson Decl. ¶¶ 10, 11. Peterson admits that while Dr. Harapanhalli was originally retained to  
19 perform similar work for Peterson’s prior firm, PWR did not have an engagement letter with Dr.  
20 Harapanhalli with respect to the 2012 amendment. *Id.* ¶¶ 8, 9.

21 My *in camera* review of documents submitted by the defendants discloses a different story.  
22 The documents indicate – like the retainer agreement discussed above – that Dr. Harapanhalli was  
23 working for Teikoku and not working directly for Endo or PWR. *See* Ex. 9; *see also* Exs. 11,  
24 12.<sup>19</sup> Endo and PWR have not shown that Dr. Harapanhalli was working for PWR or Endo’s in-  
25 house counsel during the relevant timeframe in order to provide *those* attorneys with assistance on  
26

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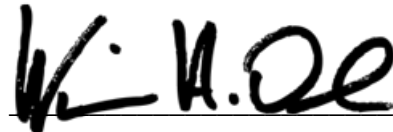
27 <sup>19</sup> A document produced to plaintiffs (after reconsideration of the initial claw back), shows that in  
28 September 2011, Teikoku reached out to Dr. Harapanhalli for his “advice” with respect to  
development of a thin Lidoderm patch. Declaration of Dena Sharp (Dkt. No 392-1), Ex. 4.

1 the 2012 amendment. The evidence shows that Dr. Harapanhalli was working for Teikoku on the  
2 proposed Citizen Petition amendment (at least through December 2011) and that Endo and PWR  
3 had to run their requests for his input through their contacts at Teikoku. Because I have found that  
4 the common interest privilege does not extend to documents shared between Teikoku and Endo  
5 regarding the Citizen Petition and its amendments, all Endo communications between Endo and/or  
6 PWR and Dr. Harapanhalli must be produced.

7 In accordance with the rulings and guidance provided in this Order, Endo and Teikoku  
8 must provide the improperly withheld or clawed-back documents and communications to plaintiffs  
9 within thirty (30) days of the date of this Order.

10 **IT IS SO ORDERED.**

11 Dated: March 7, 2016

A handwritten signature in black ink, appearing to read "W. H. Orrick", written over a horizontal line.

12  
13 WILLIAM H. ORRICK  
14 United States District Judge  
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